

**REMARKS**

Claims 45-61 are amended herein to correct informalities in the claims. Support for the amendment to claim 45 to include the definition of the “Q” variable can be found in the original claims, for example, original claim 1.

New claims 62-69, directed to a method of treatment using the claimed compounds are added herein in response to the Examiner’s statement that method claims may be added in response to the Office Action, which will be joined with the compound claims if allowed. New claims 62-69 are supported by original claims 34-37, 39 and 41. Hence no issues of new matter are presented. Accordingly, Applicants respectfully request joinder thereof.

Upon entry of the amendment, claims 45-69 will be all of the claims pending in the application.

**I. Priority**

On page 2 of the Office Action, it states that the application filed under former 37 C.F.R. § 1.60 lacks the required reference to the prior application. Applicants submit that this statement appears to be an error by the Examiner since the application was filed under 37 C.F.R. § 1.53(b) and the specification was amended to include the statement regarding the required reference to the prior application in the Preliminary Amendment filed on January 4, 2002. Applicants respectfully request clarification regarding this matter.

**II. Claim Rejections Under 35 U.S.C. § 112**

Claims 45-61 are rejected under 35 U.S.C. § 112, second paragraph as allegedly being indefinite due to various informalities in the claims. Specifically, the Examiner states that the

definition of the variable “Q” is missing from the claims; the word “derivative” should be replaced with “compound”; and clarification is requested regarding the parentheses in claim 45.

The claims are amended herein in accordance with the suggestions of the Examiner.  
Accordingly, Applicants respectfully request withdrawal of the rejection.

### **III. Prior Art**

On page 3 of the Office Action the Examiner states that the claimed compounds differ from the prior art compounds disclosed in US 4,851,401, in having “Q” as C(F), whereas the prior art teaches no substitution.

The claims are amended herein to include the definition of Q as shown in the original claims, thereby distinguishing the claimed invention from the prior art as indicated by the Examiner.

### **IV. Request for Joinder of Method Claims**

On page 3, second paragraph of the Office Action, the Examiner indicates that method claims will be joined with the compound claims if allowed. In view thereof, new claims 62-69 are presented herein and joinder is therefore requested.

### **V. Conclusion**

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

Amendment Under 37 C.F.R. § 1.111  
U.S. Application No. 10/035,251

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

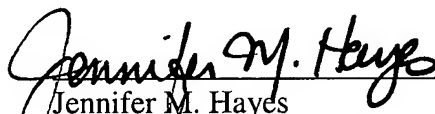
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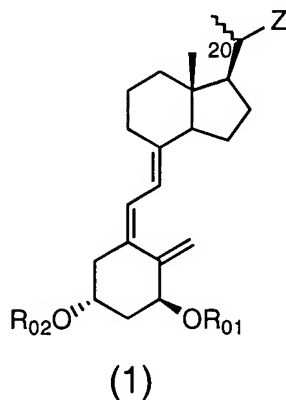
Date: January 24, 2003

**APPENDIX**  
**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

**IN THE CLAIMS:**

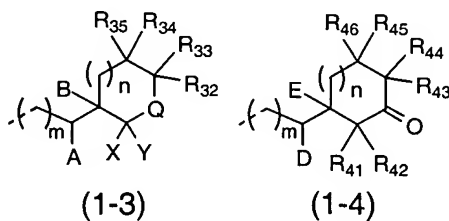
**The claims are amended as follows:**

45. (Amended) A vitamin D<sub>3</sub> ~~derivative compound~~ expressed by the following general formula (1) or pharmaceutically permissible solvates thereof,



{wherein, R<sub>01</sub> and R<sub>02</sub> are each independently a hydrogen atom, a trimethylsilyl group, a triethylsilyl group, a t-butyldimethylsilyl group, an acetyl group, a methoxymethyl group or a tetrahydro-4H-pyran-2-yl group;

Z is one out of the following formulae (1-3) and (1-4),



in the above formulae (1-3) and (1-4),

m is an integer of 0 to 2;

n is an integer of 0 to 2;

Q expresses >C(-F)-R<sub>31</sub> or >N-R<sub>31</sub>, and herein R<sub>31</sub> is a hydrogen atom, a hydroxyl group, a trifluoromethyl group, a pentafluoroethyl group, a C<sub>2</sub>-C<sub>5</sub> acyloxy group, a C<sub>1</sub>-C<sub>4</sub> alkyloxy group or a C<sub>1</sub>-C<sub>4</sub> alkyl group which may be substituted with a hydroxy group, a C<sub>2</sub>-C<sub>5</sub> acyloxy group or a C<sub>1</sub>-C<sub>4</sub> alkyloxy group;

R<sub>32</sub>, R<sub>33</sub>, R<sub>34</sub> and R<sub>35</sub> are identical to or different from each other, and they are a hydrogen atom, a hydroxyl group, a C<sub>1</sub>-C<sub>4</sub> alkyl group or a C<sub>2</sub>-C<sub>5</sub> acyloxy group;

A and B are identical to or different from each other, and they express a hydrogen atom or a hydroxyl group, or together express a single bond and form a double bond in cooperation with the single bond already shown in the formula;

X and Y together express a carbonyl group in cooperation with the carbon atom to which they are bonded, one of them is a hydrogen atom and the other is a hydroxyl group, or one of them is a hydrogen atom and the other is a C<sub>2</sub>-C<sub>5</sub> acyloxy group;

R<sub>41</sub> and R<sub>42</sub> are identical to or different from each other, and they express a hydrogen atom, a hydroxyl group, a trifluoromethyl group, a pentafluoroethyl group, a C<sub>2</sub>-C<sub>5</sub> acyloxy group, a C<sub>1</sub>-C<sub>4</sub> alkyloxy group or a C<sub>1</sub>-C<sub>4</sub> alkyl group which may be substituted with a hydroxyl group, a C<sub>2</sub>-C<sub>5</sub> acyloxy group or a C<sub>1</sub>-C<sub>4</sub> alkyloxy group, or both the members together express a

C<sub>1</sub>-C<sub>5</sub> alkylidene group, or they express a C<sub>3</sub>-C<sub>6</sub> cyclic alkyl group in cooperation with the carbon atom to which they are bonded;

R<sub>43</sub> and R<sub>44</sub> are identical to or different from each other, and they express a hydrogen atom, a hydroxyl group, a trifluoromethyl group, a pentafluoroethyl group, a C<sub>2</sub>-C<sub>5</sub> acyloxy group, a C<sub>1</sub>-C<sub>4</sub> alkyloxy group or a C<sub>1</sub>-C<sub>4</sub> alkyl group which may be substituted with a hydroxyl group, a C<sub>2</sub>-C<sub>5</sub> acyloxy group or a C<sub>1</sub>-C<sub>4</sub> alkyloxy group, or both the members together express a C<sub>1</sub>-C<sub>5</sub> alkylidene group, or express a C<sub>3</sub>-C<sub>6</sub> cyclic alkyl group in cooperation with the carbon atom to which they are bonded;

R<sub>45</sub> and R<sub>46</sub> are identical to or different from each other, and they express a hydrogen atom, a hydroxyl group, a trifluoromethyl group, a pentafluoroethyl group, a C<sub>2</sub>-C<sub>5</sub> acyloxy group, a C<sub>1</sub>-C<sub>4</sub> alkyloxy group or a C<sub>1</sub>-C<sub>4</sub> alkyl group which may be substituted with a hydroxyl group, a C<sub>2</sub>-C<sub>5</sub> acyloxy group or a C<sub>1</sub>-C<sub>4</sub> alkyloxy group;

D and E express each a hydrogen atom, D is a hydroxy group and E expresses a hydrogen atom, D and E together express a single bond and express a double bond in cooperation with the single bond already shown in the formula, or E and R<sub>41</sub> together express a single bond and express a double bond in cooperation with the single bond already shown in the formula, wherein D expresses a hydrogen atom or a hydroxy group; and R<sub>42</sub> expresses a hydrogen atom, a hydroxyl group, a trifluoromethyl group, a pentafluoroethyl group, a C<sub>2</sub>-C<sub>5</sub> acyloxy group, a C<sub>1</sub>-C<sub>4</sub> alkyloxy group or a C<sub>1</sub>-C<sub>4</sub> alkyl group which may be substituted with a hydroxyl group, a C<sub>2</sub>-C<sub>5</sub> acyloxy group or a C<sub>1</sub>-C<sub>4</sub> alkyloxy group,}

with the proviso that the following compound (a) is excluded,

(a) a compound in which the groups of one combination out of R<sub>32</sub> and R<sub>33</sub>, R<sub>34</sub> and R<sub>35</sub>, R<sub>41</sub> and R<sub>42</sub>, R<sub>43</sub> and R<sub>44</sub>, and R<sub>45</sub> and R<sub>46</sub> are both hydroxy groups, both alkyloxy groups, or a hydroxy group and an alkyloxy group.†

46. (Amended) A vitamin D<sub>3</sub> ~~derivative~~ compound or a pharmaceutically permissible solvate thereof described in Claim 45, wherein, in the above formula (1), Z is (1-3)

47. (Amended) A vitamin D<sub>3</sub> ~~derivative~~ compound or a pharmaceutically permissible solvate thereof described in Claim 45, wherein, in the above formula (1), Z is (1-4).

48. (Amended) A vitamin D<sub>3</sub> ~~derivative~~ compound or a pharmaceutically permissible solvate thereof described in one out of Claims 45, 46 and 47, wherein, in the above formula (1), R<sub>01</sub> and R<sub>02</sub> are both hydrogen atoms.

49. (Amended) A vitamin D<sub>3</sub> ~~derivative~~ compound or a pharmaceutically permissible solvate thereof described in one out of Claims 45, 46 and 47, wherein, in the above formula (1), m is 0 or 1.

50. (Amended) A vitamin D<sub>3</sub> ~~derivative~~ compound or a pharmaceutically permissible solvate thereof described in one out of Claims 45, 46 and 47, wherein, in the above formula (1), n is 0 or 1.

51. (Amended) A vitamin D<sub>3</sub> ~~derivative~~ comppound or a pharmaceutically permissible solvate thereof described in Claim 46, wherein, in the above formula (1), Q is > C(-F)-R<sub>31</sub>.

52. (Amended) A vitamin D<sub>3</sub> derivative or a pharmaceutically permissible solvate thereof described in Claim 46, wherein, in the above formula (1), Q is > N-R<sub>31</sub>.

53. (Amended) A vitamin D<sub>3</sub> ~~derivative~~-compound or a pharmaceutically permissible solvate thereof described in Claim 46, wherein, in the above formula (1), R<sub>31</sub> is a hydrogen atom, a hydroxyl group or a C<sub>1</sub>-C<sub>4</sub> alkyl group which may be substituted with a hydroxy group, a C<sub>2</sub>-C<sub>5</sub> acyloxy group or a C<sub>1</sub>-C<sub>4</sub> alkyloxy group.

54. (Amended) A vitamin D<sub>3</sub> ~~derivative~~-compound or a pharmaceutically permissible solvate thereof described in Claim 46, wherein, in the above formula (1), R<sub>32</sub>, R<sub>33</sub>, R<sub>34</sub> and R<sub>35</sub> are each a hydrogen atom.

55. (Amended) A vitamin D<sub>3</sub> ~~derivative~~-compound or a pharmaceutically permissible solvate thereof described in Claim 46, wherein, in the above formula (1), A and B are both hydrogen atoms, A is a hydroxyl group and B is a hydrogen atom, or A and B together express a single bond and form a double bond in cooperation with the single bond already shown in the formula.

56. (Amended) A vitamin D<sub>3</sub> ~~derivative~~-compound or a pharmaceutically permissible solvate thereof described in Claim 46, wherein, in the above formula (1), X and Y together express a carbonyl group in cooperation with the carbon atom to which they are bonded.

57. (Amended) A vitamin D<sub>3</sub> ~~derivative~~-compound or a pharmaceutically permissible solvate thereof described in Claim 47, wherein, in the above formula (1), R<sub>41</sub> and R<sub>42</sub> are both hydrogen atoms or together express a methylene group.

58. (Amended) A vitamin D<sub>3</sub> ~~derivative~~-compound or a pharmaceutically permissible solvate thereof described in Claim 47, wherein, in the above formula (1), R<sub>43</sub> and R<sub>44</sub> are both hydrogen atoms or together express a methylene group.



59. (Amended) A vitamin D<sub>3</sub> ~~derivative compound~~ or a pharmaceutically permissible solvate thereof described in Claim 47, wherein, in the above formula (1), R<sub>45</sub> and R<sub>46</sub> are both hydrogen atoms.

60. (Amended) A vitamin D<sub>3</sub> ~~derivative compound~~ or a pharmaceutically permissible solvate thereof described in Claim 47, wherein, in the above formula (1), D and E are both hydrogen atoms, D and E together express a single bond and form a double bond in cooperation with the single bond already shown in the formula, or D is a hydrogen atom and E and R<sub>41</sub> together express a single bond and express a double bond in cooperation with the single bond already shown in the formula.

61. (Amended) A pharmaceutical composition composed of a vitamin D<sub>3</sub> ~~derivative compound~~ or pharmaceutically permissible solvate thereof described in claim 45 and a pharmaceutically permissible carrier.

**Claims 62-69 are added as new claims.**